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August 19, 2021

VIA CM-ECF

The Honorable Richard G. Andrews
District Court of Delaware
844 North King Street
Wilmington, DE 19801

In re: Sitagliptin Phosphate ('708 & '921) Patent Litigation – MDL 2902

Dear Judge Andrews,

Defendants¹ write in response to Merck's August 19, 2021 letter (D.I. 561) regarding the contested facts section of the pretrial order.

Plaintiff Merck complains about the length of Defendants' Statement of Issues of Contested Fact. The length of the statement of facts is a direct result of Merck's continuing to assert infringement of at least 33 patent claims across two separate patents. The parties are still negotiating the scope of claims and defenses to be presented at trial; in fact, Defendants reached out to Merck's counsel earlier today to schedule a call to discuss streamlining issues for trial. Reducing the number of asserted claims and defenses would itself reduce the volume of contested issues of fact.

Moreover, Defendants' current statement of contested facts is not a verbatim recitation of expert reports as Merck claims. Instead, Defendants worked hard to include the relevant issues of fact that are contested and to thereby put Merck on notice of the evidence Defendants intend to adduce at trial. While Defendants' Draft Statement of Contested Issues of Fact appropriately provides such notice, Merck's proposal to include merely a short summary of factual issues does not serve that notice function and leaves Defendants to guess at which facts Merck actually intends to prove at trial. For example, Merck's Statement of Contested Facts on alleged unexpected results of the claimed salt of sitagliptin consists of a single conclusory statement that the purportedly unexpected properties "include superior particle morphology, non-hygroscopicity, chemical stability in solution and physical thermal stability" without any further identification of supporting facts relevant to these issues and without even any limitation on the properties on which they intend to adduce evidence (based on the use of the word "include"). Merck's conclusory recital of purported unexpected results does not serve the intended purpose of putting Defendants on notice regarding the evidence that Merck actually intends to offer at trial.

Defendants propose that the parties continue to negotiate mutual narrowing of the case, and that once the case is appropriately narrowed, each side provides a detailed statement of contested issues of facts on the remaining claims and defenses sufficient to put the other side on notice of the factual issues to be proven at trial. This is consistent with several Pretrial Orders the undersigned counsel has been involved in submitting in previous cases before Your Honor. We look forward to receiving the Court's

¹ This letter is sent on behalf of Defendants Sandoz, Inc.; Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd.; Apotex Inc. and Apotex Corp.; Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd.; Sun Pharmaceutical Industries Ltd.; Ajanta Pharma Limited and Ajanta Pharma USA Inc.; and Aurobindo Pharma Limited; Aurobindo Pharma USA, Inc. (collectively, "Defendants").



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guidance on this issue.

Counsel are available at the convenience of the Court.

Respectfully,

/s/ Dominick T. Gattuso

Dominick Gattuso (#3630)

DTG/ram
cc: All counsel of record (via CM-ECF)